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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/849,282	05/19/2004	Maxine G. Moldenhauer	1032-US2	6646

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EXAMINER	
HUI, SAN MING R	
ART UNIT	PAPER NUMBER
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/23/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/849,282	MOLDENHAUER, MAXINE G	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 November 2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) *6-9* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments filed November 21, 2006 have been entered. Claims 6-9 have been added.

Election/Restrictions

Newly submitted claims 6-9 directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: the claims are directed to a method of using the herein claimed product. Claims 1-5 and claims 6-9 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the method of treating inflammatory condition of the skin can be practiced with other patentably distinct steroidal product such as hydrocortisone.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 6-9 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 5,696,105 ('105).

'105 teaches topical cream composition comprising 0.01 to 0.25% or 0.05 to 0.15% of mometasone.furoate, Hexylene glycol, 1-5% of purified water, 2 to 10% of white wax, 4-12% of lipophilic surfactant having HLB value below 5 and 0.7 to 4% of a hydrophilic surfactant having HLB value above 11 such as ceteareth-20, 0.2-2% of titanium Dioxide, 5-20% of aluminum starch octenylsuccinate, 40-70% of White Petrolatum, and sufficient phosphoric acid to adjust the pH (See col. 4, lines 15-30). '105 also teaches a topical lotion formulated using a hydro-alcoholic base comprising 10-50% of propylene glycol (See col. 3, lines 32-46; col. 5-7, Examples 1-5).

'105 does not expressly teach the viscosity of the composition as about 400,000 to about 900,000 centipoise. '105 does not expressly teach the topical composition having propylene glycol instead of hexylene glycol.

It would have been obvious to one of ordinary skill in the art at the time of invention to incorporate propylene glycol for hexylene glycol in the mometasone topical

composition. It would have been obvious to one of ordinary skill in the art at the time of invention to adjust the viscosity of the mometasone topical composition.

One of ordinary skill in the art would have been motivated to incorporate propylene glycol for hexylene glycol in the mometasone topical composition. Propylene glycol is known to be useful in formulating a mometasone topical composition. Since propylene glycol is a well-known hydro-alcoholic base for topical composition, one of ordinary skill in the art would see the substitution of propylene glycol for hexylene glycol as selection among the obvious alternatives. Furthermore, the optimization of the effect parameter (e.g., viscosity for topical composition) would be obvious as being within the purview of skilled artisan.

Response to Arguments

Applicant's arguments filed November 21, 2006 averring the cited prior art's failure to teach the use of inflammation treatment have been fully considered but they are not persuasive. The arguments are directed to the intended use of the composition. However, the instant claims are directed to composition. Therefore, although Hackler are using the composition as anti-fungal treatment, the teahcigns of Hackler still render the instant claims obvious.

Applicant's arguments filed November 21, 2006 averring the failure of the cited prior arts to teach polyethylene glycol as suitable in the topical cream formulation have been considered, but are not found persuasive. Hackler clearly teaches polyethylene glycol as one of the ingredients in mometasone topical formulation (See col. 3, lines 32-

46). '105 even teaches the specific amount range for polyethylene glycol. Therefore, the claims are considered properly rejected under 35 USC 103(a).

Applicant's arguments filed November 21, 2006 with regard to US 4,808,610 have been considered, but are not found persuasive. Firstly, the rejection does not at all based on US 4,808,610, therefore, the arguments directed towards the teachings of US 4,808,610 are considered moot. Secondly, even arguendo, Hackler cited US 4,808,610 as a reference teaching mometasone cream is well-known. Furthermore, in Hackler, propylene glycol was not taught to decrease the efficacy of mometasone. In fact, there is nowhere in Hackler teaching propylene glycol would decrease the efficacy of mometasone. Actually, propylene glycol was taught to be one of the inventions in Hackler (See col. 3, lines 33 – 61). Examiner further notes that in '610 are using oleyl alcohol/propylene glycol mixture, while Hackler does not use oleyl alcohol, so '610 cannot be the probative evidence as teaching away since the two systems are not using the same components.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1617